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FDA Makes It Official: Informed Consent Not Required for 'Minimal Risk' Studies

A ruling issued last week by the U.S. Food and Drug Administration — to implement a provision of the 21st Century Cures Act, signed into law in December 2016 — makes it legal for clinical researchers to conduct research on human subjects without obtaining informed consent when the research poses "no more than minimal risk."

By Suzanne Burdick, Ph.D.

36

INFORMED CONSENT

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Clinical researchers no longer have to obtain informed consent from human subjects when their research poses "no more than minimal risk," the U.S. Food and Drug Administration (FDA) ruled last week.

The new rule amends FDA regulations to implement a provision of the 21st Century Cures Act, which was intended to accelerate medical product development and "bring new innovations and advances to patients who need them faster and more efficiently."

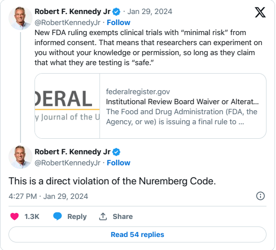
The final rule "allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects."

It also allows an institutional review board (IRB) "to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations."

"The Wuhan Cover-Up" by Robert F. Kennedy Jr. ORDER NOW

Critics — including Robert F. Kennedy Jr., chairman-on-leave of Children's Health Defense — said the move opens the door to dangerous testing on people without their knowledge or permission, beyond what U.S. citizens already endured during the rollout of experimental COVID-19 vaccines.

Kennedy tweeted:



Robert F. Kennedy Jr · Jan 29, 2024
@RobertKennedyJr · Follow
New FDA ruling exempts clinical trials with "minimal risk" from informed consent. That means that researchers can experiment on you without your knowledge or permission, so long as they claim that what they are testing is "safe."

federalregister.gov
Institutional Review Board Waiver or Alterat...
The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to ...

Robert F. Kennedy Jr
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This is a direct violation of the Nuremberg Code.

4:27 PM · Jan 29, 2024

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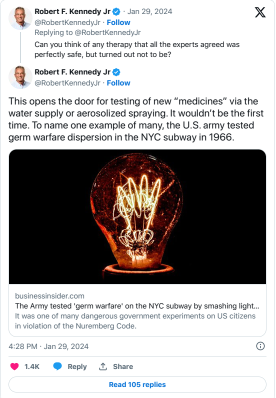

Robert F. Kennedy Jr · Jan 29, 2024
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Replying to @RobertKennedyJr
Can you think of any therapy that all the experts agreed was perfectly safe, but turned out not to be?

Robert F. Kennedy Jr
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This opens the door for testing of new "medicines" via the water supply or aerosolized spraying. It wouldn't be the first time. To name one example of many, the U.S. army tested germ warfare dispersion in the NYC subway in 1966.

businessinsider.com
The Army tested 'germ warfare' on the NYC subway by smashing light...
It was one of many dangerous government experiments on US citizens in violation of the Nuremberg Code.

4:28 PM · Jan 29, 2024

1.4K Reply Share

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The FDA said it expects the change will create "benefits in the form of healthcare advances," as studies that would otherwise not be performed if consent were required can now be undertaken.

FDA codifies law passed in 2016

Scientist James Lyons-Weiler, Ph.D., called the FDA ruling "wrong in every way possible when it comes to the culture of informed consent and human rights and medical rights."

Lyons-Weiler, president and CEO of the Institute for Pure and Applied Knowledge, teaches a course on informed consent, medical ethics and human rights.

Although the FDA's ruling is new, he said, its language comes from the Cures Act, which was signed into law on Dec. 13, 2016.

The Cures Act made statutory changes to the Federal Food, Drug, and Cosmetic Act, including amending key sections — 505(i)(4) and 520(g)(3) — so that informed consent was no longer required in clinical testing that "poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings."

The FDA's latest ruling is just "codifying that further and clarifying," Lyons-Weiler told The Defender, "because I suspect that institutional review boards and research scientists looking to do other kinds of research started claiming that they didn't have to have the oversight … if the risk to the patients was minimal, and that the FDA was swamped with requests for clarification. So this is a clarification, if you will … a bureaucratic dictate that 'yes, that's correct.'"

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Code of Federal Regulations still requires informed consent

Meanwhile, the FDA ruling and Cares Act both violate existing parts of the Code of Federal Regulations (CFR) that secures people's right to informed consent — and the CFR is stronger, legally speaking, according to Lyons-Weiler. He said:

> "46 CFR 45 … and other parts of the Code of Federal Regulations absolutely prohibit coercion of any kind into clinical research studies and protect people's right to informed consent.
>
> "That comes first. That takes precedence over [any] stated policy of any HHS [U.S. Department of Health and Human Services] director. They have to answer to the code of federal regulations because that comes from the Senate and is signed into law by the President. …
>
> "The 21st Century Cures Act and the statement by the FDA do not undo the code of federal regulations requiring informed consent."

Who decides what 'minimal risk' means?

A key issue regarding removing informed consent for "minimal risk" studies is who determines what constitutes "minimal risk."

According to the HHS:

> "Minimal Risk to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected."

HHS lists these examples of "Minimal Risk" studies:

- Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing).
- Non-interventional studies (e.g., observational studies of behavior or nutrition).
- Survey/Questionnaire studies of a non-sensitive nature.
- Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG).
- Genomic studies.
- Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function.
- Research involving the collection or meta-analysis of existing data, documents, records, pathological specimens, or diagnostic specimens to understand basic bio-behavioral processes.

IRB members are the ones who decide whether a planned study poses minimal risk or more than minimal risk.

What about kids?

Since children are not able to provide consent for themselves, parents are required to give informed permission, under federal code (45 CFR 46 Subpart D).

The FDA ruling will likely impact kids, said Lyons-Weiler, because pharmaceutical companies will likely use it to deny the parents' informed permission.

But such a move falls on faulty legal grounds, he said, because neither the Cures Act nor the FDA ruling includes the language of "permission."

"So a legal argument could be made that this doesn't apply to cases of informed permission," he said.

Who should make decisions — doctor or patient?

On his Substack, Lyons-Weiler wrote that Dr. Anthony Fauci and Christine Grady, Ph.D. — chief of the bioethics department for the National Institutes of Health — in 1986 argued that having an ethical physician in charge of decision-making was more important than informed consent:

> "Their position is that the world can trust people in white coats conducting medicine and human experimentation to be 'virtuous' while, at the same time, writing their own rules and setting their own standards for 'virtue' — and that physicians' say over the disposition of patients in medical research is more important than the patients' say because the physicians understand more."

Fauci and Grady's view runs contrary to foundational medical ethics documents, such as the Nuremberg Code, Lyons-Weiler said.

This kind of thinking — which the FDA's ruling supports by stripping away informed consent — is dangerous, Lyons-Weiler said:

> "In my view, the right to informed consent is sacred and it comes above every other policy. Because if we don't demand that, then we're on a slippery slope where they could say, 'Oh, you're on a blood pressure medication. I have to update your script.' 'Why doctor?' 'Oh, no reason. I just want to update your script.'
>
> "And then what he's really doing is telling the pharmacist, 'Stop giving the person drug A, we're going to put them on experimental drug B. I think the risk is minimal. The research team thinks the risk is minimal.'"

Dr. Robert Malone recently made a similar point when writing about the lack of informed consent during the development and rollout of COVID-19 vaccines:

> "In a historically normal regulatory and bioethical environment, this breach of international bioethical norms concerning informed consent would rise to the level of a clear-cut crime against humanity.
>
> "But in the 'through the looking glass' world of COVID post late 2019, established legal, moral and ethical norms concerning patient and citizen rights to proper informed consent have all been turned upside down."

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Big Pharma will abuse this, critics say

Critics like Lyons-Weiler say the FDA's ruling will likely be abused by Big Pharma.

"If you set this culture within one context of population-wide clinical research that informed consent is not required," Lyons-Weiler said, "of course every drug manufacturer with a popular drug — or everyone that would like to have a wide drug that's in widespread use — would love to be able to do this."

Such a culture is a ripe environment for abuse by pharmaceutical companies chasing profits, he

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said. Big Pharma will learn and they will attempt to argue that studying their product poses only "minimal risk," and they'll use "the same excuses" the vaccine makers used. "That doesn't make me a pessimist, it just makes me a realist."

Dr. Steven Kritz, an IRB chair and retired physician, agreed. He pointed out that the FDA received only about 50 comments before it finalized its ruling. "Not one of the comments mentioned exceptions to informed consent in the context of research involving a pharmaceutical product," he said.

Regardless of the FDA's ruling, all IRBs should insist that any research project involving a pharmaceutical product include informed consent, Kritz said.

The Defender asked the FDA Office of Clinical Policy what the agency would like to tell members of the public who are concerned that this unethically strips people of their right to informed consent. The office did not respond by our publication deadline.

The Defender on occasion posts content related to Children's Health Defense's nonprofit mission that features Mr. Kennedy's views on the issues CHD and The Defender regularly cover. In keeping with Federal Election Commission rules, this content does not represent an endorsement of Mr. Kennedy, who is on leave from CHD and is running as an independent for president of the U.S.

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Suzanne Burdick, Ph.D.

Suzanne Burdick, Ph.D., is a reporter and researcher for The Defender based in Fairfield, Iowa.

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BoredHousewife
4 days ago edited
This is what I'm worried about: "This opens the door for testing of new 'medicines' via the water supply or aerosolized spraying." We know they developing aerosolized vaccines.... and of course, they believe all vaccines are perfectly safe.
17 0 Reply • Share ›

KBigg → BoredHousewife
4 days ago
I was about to write the same thing. Our federal medical establishment is being run by psychopaths.
17 0 Reply • Share ›

BraveNewWhirled → BoredHousewife
3 days ago
Soon you will eat mRNA-infused broccoli. And you won't know it. They're just codifying what they've been doing to us for decades. "Minimal risk"? That's no different than "safe-n'-effective". Whatever they say becomes truth.
5 0 Reply • Share ›

Grim Fandango → BraveNewWhirled
3 days ago edited
They never share what their definition of "*safe*" or "*effective*" actually means.

Do they quantify "*Safe*" as compared to a bullet to the head?
"*This new vaccine is far safer than a bullet to the head*"

"*Effective*" as a bullet to the head?
"*This new vaccine is as effective as a bullet to the head.*"
1 0 Reply • Share ›

Popocatepet1 → BoredHousewife
4 days ago edited
Well, it doesn't, since there are multiple other codes, laws and standards that exist on informed consent. And not needing consent doesn't remove the subject's right to refuse to participate, nor does it give anybody the right to assault another person. The FDA lowering their own appallingly inadequate standards doesn't really change anything. It's just a sop for the normies.
4 0 Reply • Share ›

BoredHousewife → Popocatepet1
3 days ago
It's hard to opt out of aerial spraying.
5 0 Reply • Share ›

BraveNewWhirled → Popocatepet1
3 days ago
You seem to be operating on the assumption that we're dealing with people who are honorable, forthcoming, and respectful of human life. I don't see evidence they are honorable at all; but I see a lot of evidence they are dastardly criminals.
2 0 Reply • Share ›

Laura Pieters
4 days ago edited
Unbelievable! Minimal risk for who? If anyone is even hurt they won't be able to tie it to the experiment because they won't know they were in one!
12 0 Reply • Share ›

Popocatepet1 → Laura Pieters
4 days ago
The kafkaesque irony is of course that risk cannot be established without the trials.
4 0 Reply • Share ›

BTeboe
4 days ago
Who decides what is 'minimal?'
9 0 Reply • Share ›

aj54
4 days ago
I have an autoimmune disease. Any infection or vaccination has caused my system to go wildly hyper-reactive.I don't want anything secretly given to me without my consent!
8 0 Reply • Share ›

Grim Fandango → aj54
3 days ago
That's the amazing part of their plan - you'll never know, you'll never sue, and best of all, you'll never say NO!
2 0 Reply • Share ›

Wendy Allen
4 days ago
They don't know the risk so can't say low risk. They may secretly know it will hurt people so push the shot or drug. Parents should be allowed to choose natural help for themselves and kids, which works awesome instead of man made corrupt people's things.
8 0 Reply • Share ›

Beverly Royce
4 days ago
What criteria defines minimal risk? How would they reach that conclusion? What could possibly go wrong?! (note sarcasm)
7 0 Reply • Share ›

holisticpoet
4 days ago
This is a slippery slope. Who decides what is minimal? Will this be abided by when there is an urgency to complete a trial, or will it be overlooked to satisfy time restraints when someone deems it necessary to overlook what might be considered minimal? My advise, never take any drug if you have any reservations whatsoever.
7 0 Reply • Share ›

Venus → holisticpoet
21 hours ago
This is not a slippery slope. They have jumped off the ledge.
1 0 Reply • Share ›

drw22
4 days ago
"The FDA said it expects the change will create "benefits in the form of healthcare advances," as studies that would otherwise not be performed if consent were required can now be undertaken." - So what they're really saying is that if volunteers were told the risks, then they wouldn't do it, so bye-bye study. If people are given the facts and reject the study, then the 'scientists' have to go back and make the product less risk. They shouldn't be allowed to give it without informed consent. "Safe and effective." Where have we heard that before?
6 0 Reply • Share ›

notaluvvie
4 days ago
Nice one Big Pharma, corrupt politicians and public servants. How does one know what is minimal risk 'til the "studies" (another codeword for human experiments of unknown experimental drugs which could cause injuries and death) are undertaken? We'll know when it safe when we see their children or parents being used as human guinea pigs.
6 0 Reply • Share ›

Andreas
4 days ago
I would argue that their determination exceeds their authority under the statute that created the FDA. Like most administrative agencies, they exceed their mandate - acting as legislatures creating new law - they are rogue bordering on gross recklessness and willful lawlessness. They do redefine terms to justify criminal actions. Safe no longer means safe in its plain usage. Effective does not mean that it cures. This is a fascist takeover through the administrative bodies.
5 0 Reply • Share ›

lonerngr88
4 days ago
And who decides what is "minimal risk"? A peanut is a snack for one and a death sentence for another...
5 0 Reply • Share ›

Andreas
4 days ago
remember - to this day that assert that the covid "vaccines" are vaccines under their new definition, and that they are safe and effective . . . all three of those assertions are demonstratively false.
4 0 Reply • Share ›

Fred Secret
3 days ago
"SIgned into law December 13, 2016 - which means it was under OBAMA that this happened. RFK, I love a lot of what you do, but why not call out the administration that "signed it into law"?
3 0 Reply • Share ›

Popocatepet1
4 days ago
FDA "rules" for informed consent?
1) multiple pre-existing medical standards and codes of practice still remain.
2) the patient can still ask for any information they like, and refuse to participate for whatever reason they choose.
Ergo, FDA relaxing "rules" is no more meaningful than me relaxing my own "rules" on when I can punch somebody in the face.
2 0 Reply • Share ›

BoredHousewife → Popocatepet1
3 days ago
You seem to be missing the point.... without informed consent, you aren't required to be informed. That means not only are you not required to be informed of possible risks, you are not required to be informed that you are the subject of an experiment. Therefore, your point (2) is off base -- you don't ask for information if you don't realize that you're about to be a lab rat in the first place.
1 0 Reply • Share ›

Christine Jahnig
4 days ago
It's hard to believe that there are such evil people in this world much less in our government agencies. The only person who should decide what minimal risk is the person who is being exposed to it. But, hey, how would that person know what the risk is without full, informed consent? He wouldn't. Another stroke of evil for the purpose of making money. Criminal actions of people who should be charged with criminal offenses.
2 0 Reply • Share ›

Preston Lee
4 days ago
Does this override the Belmont Report and Nuremberg Code both of which I believe we are bound to uphold?

The Belmont report spells out the ethical principles and guidelines for the protection of human subjects of research, covered under the U.S. Code of Federal Regulations 45 CFR 46 (subpart A). The Belmont report describes informed consent as follows:
"Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness
2 0 Reply • Share ›

Voyt Regnal
4 days ago
Expect even more. We are the human cattle or lab rats (depending on circumstances) owned by certain small number of very powerful individuals.
2 0 Reply • Share ›

Ricky Ricardo
a day ago
A classic case of the fox guarding the hen house! The FDA needs to be dismantled!
1 0 Reply • Share ›

Henry Longstop
3 days ago
I'm military parlance it's called 'mission creep'.
1 0 Reply • Share ›

ME MCC
4 days ago
Hello...autonomy?? Time to check these institutions!
1 0 Reply • Share ›

jann
2 days ago
Follow the money.
"The benefits that we are able to quantify are the cost savings to IRBs because the time burdens of reviewing certain minimal risk clinical investigations under differing requirements would be reduced."

https://www.fda.gov/about-f...

I never heard about a public comment period for this change and neither did Dr. Steven Kritz, IRB chair.
https://brownstone.org/arti...

I'd enjoy hearing Dr. Kritz on CHD TV.
0 0 Reply • Share ›

Grim Fandango
3 days ago
"*What ya don't know can't hurt ~~you~~ us.*"
~FDA
0 0 Reply • Share ›

Grim Fandango
3 days ago edited
New BIG PHARMA disclaimer:
"*Ask your doctor if minimal death from participation in a secret drug research is right for you*"
0 0 Reply • Share ›

Grim Fandango
3 days ago
If this research poses "*no more than minimal risk*." then they should have no need of ignoring the informed consent requirements. There should be a long line of informed volunteers willing to step up for the good of science, and humanity.

The very fact they want the ability to covertly turn anyone into a human guinea pig tells you all you need to know.
0 0 Reply • Share ›

Gary Brown
3 days ago edited
Yes indeed so. June 5, 2023 FDA's New Rule Allows for Medical Research Without Informed Consent

Studies cannot pose more than minimal risk to humans and must include appropriate safeguards to protect the rights, safety, and welfare of those involved.

https://www.theepochtimes.c...
0 0 Reply • Share ›

Jorge Cerra
3 days ago
minimal risk like, for example, that of covid "vaccines" and their 17 million deaths.
0 0 Reply • Share ›

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